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SECTION 10

510(k) SUMMARY K 020071

This 510(k) summary of safety and effectiveness for the Viridis Derma (frequency doubled Nd:YAG) laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: QUANTEL MEDICAL

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Contact Person: Mr. Jean Abascal
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Preparation Date: December 2001
(of the Summary)

Device Name: Viridis Derma

Common Name: Frequency Doubled Nd:YAG Surgical Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code: GEX
Panel: 79

Predicate device: The Viridis Laser (K001784): Nuvo-Lase 660 Laser System (K970667) COMPACT KTP Laser (K983020); DioLite 532 Laser System (K964074); Nidek Dio-Lite 60 Laser System (K981447); Altus Family of CoolGlide Aesthetic Lasers (K003202)

Device description: The Viridis Derma frequency doubled Nd:YAG laser emits a beam of coherent light at 532 microns.

Indications: The Viridis Derma laser is intended for photocoagulation of pigmented lesions in dermatology.

These include the following applications:

Benign Vascular Lesions	Facial Telangiectasias
Port Wine Stains	Café au-lait
Erythrosis	Benign Pigmented Lesions
Cuperosis	Senile Lentigo
Keratoses	Hemangiomas (spider and cherry/
Dermatosis Papulosis Nigra (DPN)	strawberry)

Leg Telangiectasia - only as a complement to sclerotherapy and for small superficial red vessels

The Viridis Derma laser will be labeled as a prescription device as follows:

CAUTION: Federal (US) law restricts the use of this device to licensed professionals

Performance Data: None required.

CONCLUSION:

Based on the information in the notification Quantel Medical concludes that the Viridis Derma frequency doubled Nd:YAG laser is substantially equivalent to the Viridis laser and to other cited legally marketed predicates, under the conditions of intended use (above).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quantel Medical
c/o Mr. Roger W. Barnes
342 Sunset Bay Road
Hot Springs, AR 71913

APR - 5 2002

Re: K020071
Trade/Device Name: Viridis Derma Laser
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 7, 2002
Received: January 9, 2002

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020071

Device Name: Viridis Derma (Frequency doubled Nd:YAG laser)

Indications for Use Statement:

The Viridis Derma laser is intended for photocoagulation of pigmented lesions in dermatology.

These include the following specific applications:

Benign Vascular Lesions	Facial Telangiectasias
Port Wine Stains	Café au-lait
Erythrosis	Benign Pigmented Lesions
Cuperosis	Senile Lentigo
Keratoses	Hemangiomas (spider and cherry/ strawberry)
Dermatosis Papulosis Nigra (DPN)	

Leg Telangiectasia - only as a complement to sclerotherapy and for small superficial red vessels

The Viridis Derma laser is labeled as a prescription device as follows:

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

Mariam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020071

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)